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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,631	03/01/2002	Stephan Jaeger	1803-335-999	3750

24341 7590 01/28/2004

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EXAMINER	
WILDER, CYNTHIA B	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,631	JAEGER, STEPHAN	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10/02 & 1* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

FINAL ACTION

1. Applicant's amendment filed on November 7, 2003 is acknowledged. Claims 15-19 have been added. Claims 6-8 have been amended. Claims 1-5 have been canceled. All of the amendments and arguments have been thoroughly reviewed and considered but they are not found persuasive for the reasons that follow. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

This action is made Final.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous Objections and Rejections

3. The objection to the information disclosure statement is withdrawn in view of applicant's submission of English -language translation of the abstracts of the documents. The objection to the specification is withdrawn in view of Applicant's amendments to the specification. The claim rejections under 35 USC 101 directed to claims 6-8 as being drawn to a non-statutory subject matter are withdrawn in view of applicant's amendment to the claims. The claim rejections under 35 USC 112 first paragraph directed to claims 6-14 as lacking adequate written description is withdrawn in view of Applicant's amendment of the claims and arguments. The prior art rejections under 35 USC 102(b) as being anticipated by Mullis et al. is maintained and discussed below. The prior art rejections under 35 USC 102(b) as being anticipated by Nadeau et al are maintained and discussed below. The prior art rejections under 35 USC 102(b) as being anticipated by Tsang et al. are maintained and discussed below.

Claim Rejections - 35 USC § 102

4. Once again, claims 6-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Mullis (US 4,683,202, July 28, 1987). Regarding claims 6-14, Mullis et al. teach a control nucleic acid sequence and composition comprising a target nucleic acid and a control nucleic acid sequence for use in an amplification reaction wherein said control nucleic acid sequence comprises at least one contiguous sequence of at least 8 nucleotides in length essentially parallel complementary to said target nucleic acid region (see example 1, col. 15, lines 45-56) and wherein said target nucleic acid region comprises a primer binding site and the control nucleic acid sequence comprises a sequence that is parallel complementary to the primer binding site of the target nucleic acid (see example, col. 15, lines 45-56). The reference further teaches wherein the target region comprises a probe binding site and the control nucleic acid sequence comprises a sequence that is parallel complementary to the probe binding site of the target nucleic acid, (see example 5, lines 16-23) and wherein the composition further comprises primers for amplification (example 5, col. 21, lines 30-38). Therefore, Mullis meets all of the claimed limitations of claims 6-12 of the instant invention.

Applicant's Traversal

5. Applicant traverses the rejections on the following grounds: Applicant states that the Office cites three passages from Mullis as allegedly teaching a control nucleic acid sequence comprising a sequence that according to the Patent Office, is essentially parallel complementary to a target nucleic acid region. Applicant contends that Mullis et al feature the use of primers that hybridize to their target nucleic acid. Applicant states that the primers have an anti-parallel, complementary orientation to one or another DNA strand of a target nucleic acid. Applicant

cites a passage from Mullis and states that the cited passage features the amplification of a 25 base pair double stranded DNA sequence, wherein the strands are in an anti-parallel complementary orientation relative each other, that is contained in a larger 47 base pair restriction fragment. Applicant contends that the eleven base pair primers and thirteen base primers taught at lines 55-56 each hybridize to one or the other of the single-stranded 25 base pair DNA strands. Applicant states that no parallel complementary control nucleic acid as recited in claims 6-12 is taught or suggested by Mullis. Applicant further adds that Mullis presents two oligonucleotides, that other than the three mismatches are antiparallel complementary to each other. Applicant further states that at col. 21, lines 30-38, Mullis features a primer pair for amplification of a beta-globin sequence from genomic DNA. Applicant argues that to amplify the beta-globin sequence, the primers featured in Mullis at col. 21, must anneal to local sequences within the larger beta-globin sequence. Applicant states that therefore, these primers featured in Mullis are anti-parallel (not parallel) complements to local sequences within the beta-globin sequence. Applicant finally concludes that because Mullis features anti-parallel complementary primers and oligonucleotides, Mullis does not teach or suggest each and every limitation in any one of claims 6-12. Applicant respectfully request the rejections be withdrawn.

Examiner's Response

6. Applicant's amendment filed on November 7, 2004 has been fully considered but it is not found persuasive for the reasons that follows: The courts have established that during patent examination, the claims must be interpreted broadly as reasonably allow *(In re Zletz, 893 F.2d321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989)*. In this case, the claims broadly recites a control nucleic acid that is "*essentially* parallel complementary" to any non-specific nucleic acid

sequence or a complementary sequence of another sequence. The claims as broadly written are full of "intended use" term with relations to an unclaimed target sequence, which is only recited in the preamble. MPEP states that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Therefore, the isolated control nucleic acid of the instant invention is only speculated to be parallel complementary to a target nucleic acid, but is not limited by any means to a specific target sequence and can simply be considered a probe. Moreover, the claims do not recited what is required or specific properties of the control nucleic acid that would distinguish it from simply a probe or primer, regardless of it's orientation. While the specification, as noted by Applicant, provides an ambiguous definition of the term "essentially parallel complementary", the claim as written is not limited in such a way as disclosed in the specification. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, in view of the foregoing, Mullis et al meets the limitations of the claims and accordingly, the rejections under 35 USC 102(b) are maintained.

Claim Rejections - 35 USC § 102

7. Once again, claims 6, 8, 9, 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Nadeau et al. (5,840,487, November 24, 1998). Regarding claims 6, 8, 9, 11, Nadeau et al teach a control nucleic acid and composition comprising a target nucleic acid and control nucleic

acid for use in an amplification reaction wherein the control nucleic acid comprises at least one contiguous sequence of at least 8 nucleotides in length essentially parallel complementary to the target nucleic region and wherein said target nucleic acid region further comprises a probe binding site and said control nucleic acid comprises a sequence that is parallel complementary to the probe binding site of the target nucleic acid (see column 8, lines 1-41). Therefore, Nadeau et al meets all of the claimed limitations of claims 6, 8, 9, 11 of the instant invention.

Applicant's Traversal

8. Applicant's amendment filed on November 7, 2003 is acknowledged. Applicant traverses the rejection on the following grounds: Applicant states that not one of the reference cited by the Patent Office teaches or suggests a control nucleic acid that comprises at least one contiguous sequence of at least 8 nucleotides in length essentially parallel complementary to a target nucleic acid region such as recited in claim 6. Applicant contends that the importance of the meaning of the term "parallel complementary" in understanding why none of the reference anticipates any one of claims 6-12. Applicant states that the specification at page 8, explains that a first nucleic acid sequence is the parallel complement to a second nucleic acid sequence of the complementary stand of the second nucleic acid sequence. Applicant states that parallel complementary sequences do not hybridize or anneal together as shown in Figure 1 of the specification, since two sequences must be anti-parallel (not parallel) complementary sequences to each other to allow hybridization or annealing as shown in the exhibit.

Examiner's Response

9. Applicant's amendment filed on November 7, 2004 has been fully considered but it is not found persuasive for the reasons previously discussed above at # 6. As stated earlier, the claim

as broadly written are not limited in the way applicant contends. The claims do not specifically point to a specific property of the control nucleic acid. The claim as broadly written recites limitations that are an "intended use" which carries no patentable weight and does not specify or particularly relate to a desired target sequence. Likewise, the claims broadly relies on the meaning of the tem "essentially parallel complementary" which can be interpreted in numerous way to simply mean a probe or primer in the context of the claim language. As previously discussed, while the specification provides an ambiguous example of a sequence considered "parallel complementary", the claim as written is not limited in such way. MPEP states that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, in view of the foregoing, the rejection under 35 USC 102(b) as being anticipated by Nadeau et al is maintained.

Claim Rejections - 35 USC § 102

10. Once again, claims 6, 7, 9, 10, 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsang (5,837,442, November 17, 1998). Regarding claims 6, 7, 9, 10, 12-14, Tsang teaches a control nucleic acid sequence, composition and kit, wherein said control nucleic acid comprises at least one contiguous sequence of at least 8 nucleotide in length essentially parallel complementary to a target nucleic region. The reference further teaches wherein said target nucleic acid region comprises a primer binding site and said control nucleic acid sequence comprises a sequence that is parallel complementary to the primer binding site of said target nucleic acid or to the complementary strand of said target nucleic acid (Col. 5, lines 24-45). The reference further teaches wherein the nucleic acid sequences are in the form of a kit (col. 8, lines

17-27). Therefore, Tsang et al. teach the limitations of the claimed invention of the claims recited above.

Applicant's traversal

11. Applicant traverses the rejections on the following grounds: Applicant states that the Patent Office alleges that Tsang et al. teaches a control nucleic acid sequence comprising at least one contiguous sequence of at least 8 nucleotides in length essentially parallel complementary, according to the Patent Office, to said target nucleic acid region. Applicant states that Tsang et al. teach an upstream primer for use in conjunction with one of two disclosed downstream primers for the amplification of HCV nucleic acid. Applicant state that as explained by Tsang et al., these primers hybridize to relatively conserved regions with the 5' untranslated region of the HCV genome and enable the amplification of nucleic acids from the known HCV isolates. Applicant states that therefore, since these primers must be anti-parallel (not parallel) complementary in order to hybridize to each other. Applicant concludes that no parallel complementary control nucleic acid recited in claims 6-12 of the instant application is taught or suggested by Tsang et al.

Examiner's Response

12. Applicant's amendment filed on November 7, 2004 has been fully considered but it is not found persuasive for the reasons previously discussed above at # 6 and # 9. As stated earlier, the claim as broadly written are not limited in the way applicant contends. The claims do not specifically point to a specific property of the control nucleic acid. The claim as broadly written recites limitations that are an "intended use" which carries no patentable weight and does not specify or particularly relate to a desired target sequence. Likewise, the claims broadly relies on

the meaning of the tem "essentially parallel complementary" which can be interpreted in numerous way to simply mean a probe or primer in the context of the claim language. As previously discussed, while the specification provides an ambiguous example of a sequence considered "parallel complementary", the claim as written is not limited in such way. MPEP states that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, in view of the foregoing, the rejection under 35 USC 102(b) as being anticipated by Tsang et al is maintained.

New Ground(s) of Rejections

THE NEW GROUND(S) OF REJECTIONS WERE NECESSITATED BY APPLICANT'S AMENDMENT TO THE CLAIMS:

Claim Rejections - 35 USC § 11: New Matter

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. The specification is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's amendment to the specification by inserting before the first line of the

specification that follows the title the following paragraph: "This application claim priority under 35 USC 119(a)-(c) to European Application No. 01 105 172.9, filed March 2, 2001, the content of which is hereby incoroprated by reference in its entirety" introduces new matter into the disclosure of the invention under 35 USC 112 first paragraph. Specifically, the amendment to the specification to incorporate the priority document by reference in its entirety to the specification adds new matter because it changes the content of the specification. Likewise, Applicant's cross-reference to the priority document is improper as indicated under Rule 1.78. Rule 1.78 states that the priority document must be submitted during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. The time period is not extendable, unless the reference required by this paragraph is included in an application date sheet (Rule 1.76). Therefore, in view of the foregoing, the specification as amended would not have suggested to the skilled artisan that the Applicant was in possession of the claimed invention as of the filing date.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsang (5,837,442, November 17, 1998). Regarding claims 15-19, Tsang teaches a control nucleic acid

sequence, composition and kit, wherein said control nucleic acid comprises at least one contiguous sequence of at least 8 nucleotide in length essentially parallel complementary to a target nucleic region. The reference further teaches wherein said target nucleic acid region comprises a primer binding site and said control nucleic acid sequence comprises a sequence that is parallel complementary to the primer binding site of said target nucleic acid or to the complementary strand of said target nucleic acid (Col. 5, lines 24-45). The reference further teaches wherein the nucleic acid sequences are in the form of a kit and includes a control nucleic acid specific probe, enzymes and reaction buffer (col. 8, lines 17-27). Therefore, Tsang et al. teach the limitations of the claimed invention of the claims 15-19.

Conclusion

16. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (703) 305-1680. After January 14, 2004, the examiner cam be reached at (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0196.

BJ FORMAN, PH.D.
PRIMARY EXAMINER